

K210793 VIDAS NEPHROCHECKJul 8, 2022
479 days to decisionK210793 · Product code: **PIG** · Chemistry
Source: <https://www.510kdatabase.net/k210793/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acute Kidney Injury Test System (PIG)
Date received	Mar 16, 2021
Decision date	Jul 8, 2022
Days to decision	479 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biom?rieux SA
Location	Marcy-L'?toile, FR
Contact	Julien Thao My
510(k) history	3 submissions · 3 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210793/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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